

REMARKS

Claims 1-11, 21-27 and 29-33 remain pending in this application. The summary of the Office Action does not contain a reference to claims 31-33. Claims 1 and 24 have been amended to indicate that a function of having fibres wound around the whole of the flexible portion and the at least one less flexible portion is to reinforce the prosthesis. Support for this feature can be found, for example, at page 8, lines 19-22 and page 9, lines 5-8. Accordingly, no new matter has been introduced by these amendments.

Although claim 23 is stated to be rejected in the Office Action Summary, no rejection has been applied to claim 23.

Claims 1-11, 21, 24-27 and 29-33 have been rejected under 35 U.S.C. § 103 as being unpatentable over Dickman (U.S. Patent No. 7,066,960) in view of Stubstad et al. (U.S. Patent No. 3,867,728). The Office has argued that Dickman discloses a number of features of the present claims that simply are not found in Dickman, nor has the Office established any sound basis for its conclusions.

The Office argues that Dickman discloses a disc prosthesis that has a flexible section 52 and less flexible portions 103, 104. If the prosthesis comprises these three elements, then it is not appropriate to suggest (as stated in the Office Action - page 3) that the prosthesis is fiber reinforced with a sheath 51 because sheath 51 clearly surrounds only the flexible section 52, not the composite prosthesis. (See, e.g., Figs 5, 10 and col. 8, line 55 et seq.).

The Office states that the fiber material used as a fabric reinforcement of the core has a low modulus and is "considered capable of absorbing hydrogel monomers." The Office has not established any factual basis for such an unsupported conclusion, or

even suggested a reason that a person skilled in the art would consider such a property desirable from the teachings of the prior art. It is manifestly improper to simply assume such a property is inherent simply because it is not addressed in the prior art teachings. Similarly, it is not understood how the Office is led to the conclusion that the hydrogel core of Dickman would have the recited swelling characteristics simply because it can remain liquid or in semi-liquid state before it is impregnated into the fabric. There is no necessary relationship between the solubility or natural state of a hydrogel polymer and its swelling characteristics, yet the Office appears to make this unwarranted assumption.

The Office acknowledges that Dickman fails to disclose the less flexible portion is also covered in fibers. Although this may be true, the claims require more than simple coverage with fibers since the claimed prosthesis is characterized by fibers "wound around the whole of the flexible portion and the at least one less flexible portion to reinforce the prosthesis" (claim 1, for example). Simply having fibres on the less flexible portion may be adequate to accomplish the purpose of the fibers described in Stubstad et al. (col. 4, lines 18-21) of enhancing tissue ingrowth, but it would not accomplish the claimed function of reinforcing the prosthesis.

Stubstad et al. teaches that a mesh of Dacron filament can be wound around the resilient core 15, much like in Dickman. However, the top and bottom elements 11 and 12 are provided with a fabric surface by folding a mesh layer on the surfaces of the core and stitching all the elements together at the periphery of the prosthesis (see e.g., Fig. 1, col. 7, line 38 to col. 8, line 41). There is no suggestion of securing the elements together or reinforcing the prosthesis by winding fibres around the whole of the

prosthesis that comprises at least one flexible portion and at least one less flexible portion.

Although the Office states, in Response to Arguments (page 5 of Office Action) that when Stubstad et al. discloses a filament 29 is used to thoroughly stitch through the mesh of the upper and lower endplates, it can be considered to meet the recited feature that fibres are wound around the whole of the flexible portion and the at least one less flexible portion to reinforce the prosthesis, this is clearly contrary to the plain meaning of the terms used in the claims. Stubstad et al. clearly shows (Fig. 1) and teaches (e.g., at col. 8, lines 32-41) that filament 29 is stitched through the fabric at the sides and top and the assembly is subjected to vulcanizing heat to hold the elements together. Fibres are not wound around the whole of the prosthesis to reinforce it as in the claimed invention.

Applicants have clearly defined and illustrated the terms used in the claims, and they define an arrangement of parts much different in structure and method of preparation than is taught by any teaching of Dickman or Stubstad et al., taken alone or in any combination. Although claims in pending applications are interpreted as broadly as their terms reasonably allow, when "the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art." In re Zletz, 893 F.3d 319, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). The Office position relative to the limitation that the fibres "are wound around the whole" not only distorts the plain meaning of these terms, but is contrary to the meaning that Applicants have shown and stated these terms are intended to have.

The Office acknowledges that neither Dickman nor Stubstad et al. disclose that fibres are made of polyurethane, but argues that the selection of a known material on the basis of its suitability for the intended use would be obvious. However, although polyurethane is a known material, there is no showing that it would be suitable for the use according to the claimed invention. This is particularly true where neither Dickman nor Stubstad et al. teach the use of fibres for winding around the whole of the prosthesis.

With respect to claims 24-27, 29 and 30, the Office incorrectly observes that applicants are claiming an article of manufacture and not a process of making a prosthesis. However, a closer review of claims 24-26 will reveal that these claims are directed to a process, and the claimed steps of that process must be considered and given weight in any determination of patentability. In addition, even where the claim is directed to a product, it is improper to ignore procedural limitations (e.g., winding around the whole of the prosthesis) that inherently lead to a different article than is disclosed by the prior art.

For all the reasons discussed above, neither Dickman nor Stubstad et al., either alone or in any combination, teach or suggest the claimed invention. In the absence of a *prima facie* case of obviousness, this rejection should be withdrawn.

Claims 1, 21 and 22 have been rejected as being unpatentable over Dickman in view of Stubstad et al., Bao et al. (U.S. Patent No. 5,047,055) and Stoy (U.S. Patent No. 6,264,695). It is assumed that the Office also intended to include claim 23 in this rejection. The Office argues that Dickman and Stubstad et al. disclose the claimed invention except for reducing the volume of the implant prior to insertion by soaking the

implant in a salt bath. Bao et al. is stated to teach reducing the volume of a prosthesis by dehydration prior to implanting, while Stoy is stated to teach using a salt bath to reduce the volume of the prosthesis.

This rejection also is traversed because neither Bao et al. nor Stoy teach or suggest any of the deficiencies in the teachings of Dickman and Stubstad et al. discussed above, so these claims are patentable for the same reasons discussed above for claim 1. In addition, the teachings of Bao et al. relied on by the Office relate only to implanting a nucleus of an invertebral disc and not the complete disk itself as recited in claims 21-23. In addition, the teachings of Stoy relate to methods for plasticizing swellable plastics, and do not teach or suggest that a hydrogel can or should be dehydrated prior to implementation. For these additional reasons, the references relied on by the Office fail to establish a prima facie case of obviousness. Accordingly, this rejection should be withdrawn.

Prompt and favorable reconsideration of this application is respectfully requested.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: Charles E. Van Horn
Charles E. Van Horn
Reg. No. 40,266